MAY - 5 2000

K001144

SECTION II

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness for the **UltraEdge Keratome Blade (Model No. 374803 – ACS)**, which is intended to be used as a replacement blade for the Chiron Vision's Automatic Corneal Shaper (ACS) Keratome System, is provided as required per Section 513(1)(3) of the Food, Drug and Cosmetic Act.

1. Submitter:

LaserSight Technologies, Inc.
3300 University Blvd. Suite 140
Winter Park, Fl 32792

2. Proprietary Name: UltraEdge Keratome Blade **(Model No. 374803 – ACS)**

Common Name: Keratome

Classification Name: Keratome, 21 CFR 886.4370.

4. Predicate or Legally Marketed Devices:

- Surgistar Microkeratome Blade – Surgistar Inc. (K992978)
- ACS Keratome Blade – Chiron Vision.(K941550)
- UltraEdge Keratome Blade (Model No. A98027-UltraShaper) – LaserSight Technologies, Inc. (K990227)

5. Description of Device:

The **UltraEdge Keratome Blade (Model No. 374803 – ACS)** is a replacement blade for use with Chiron Vision's ACS Keratome System and is fabricated from stainless steel

6. Indication For Use

The **UltraEdge Keratome Blade (Model No. 374803 – ACS)** is a single-use replacement blade for use with AC-powered Chiron Vision ACS Keratome System that is intended to shave a partial lamellar resection of the cornea.

7. Substantial Equivalence

The **UltraEdge Keratome Blade** is substantially equivalent to the following predicate LaserSight and competitive devices:

1. Surgistar Microkeratome Blade – Surgistar Inc. - (510(k) # K 992978)
2. ACS Keratome Blade - Chiron Vision - (510(k) # K 941150)
3. UltraEdge Keratome Blade (Model No. A98027-UltraShaper) LaserSight Technologies, Inc. – 510(k) # K990227

Features	UltraEdge Keratome Blade System (Model No. 374803 – ACS)	Predicate UltraEdge Keratome Blade (Model No. A98027-UltraShaper)	Predicate Chiron Vision ACS Keratome Blade	Predicate Surgistar Microkeratome Blade	Equivalent
Indications for Use	Same	Same	Same	Same	Yes
Materials	Same	Same	Same	Same	Yes
Design Features	Same	Same	Same	Same	Yes
Operation Principle	Same	Same	Same	Same	Yes
Sterilization method	EtO	Gamma Radiation	EtO	Gamma Radiation	Yes
Patient contact portion of the device	Yes	Yes	Yes	Yes	Yes
510(k) #	-	K990227	K941550	K992978	-

Dimensional and Sharpness Equivalency Chart

Attribute	UltraEdge Keratome Blade (Model No. 374803-ACS)	Predicate UltraEdge Keratome Blade (Model No. A98027-UltraShaper)	Predicate Chiron Vision ACS Keratome Blade	Predicate Surgistar MicroKeratome Blade
Length	0.444" ± 0.001	0.444" ± 0.001	0.444" ± 0.001	0.445"
Width	0.3145" ± 0.001	0.3135" ± 0.001	0.3145" ± 0.001	0.313"
Thickness	0.0100" ± 0.002	0.0100" ± 0.002	0.0100" ± 0.002	0.010"
Bevel	10.6° to 12.8°	10.6° to 12.8°	10.6° to 12.8°	11.5°
Mounting Hole Length	0.2805 ± 0.0005	0.2800 ± 0.001	0.2805 ± 0.0005	0.2805 ± 0.005
Mounting Hole Width	0.0865 ± 0.0006	0.860 ± 0.0002	0.0865 ± 0.0006	.0866 ± 0.005
Mounting Hole Radius	0.0433 ± 0.0003	0.0430 ± 0.0001	0.0433 ± 0.0003	.0433 ± 0.005
Sharpness*	8.16 (1.15)	8.16 (1.15)	8.13 (3.22)	Not Available

* Sharpness expressed as average grams force, standard deviation in parenthesis

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2000

Mr. Sam A. Mirza
Manager, Regulatory Affairs
LaserSight Technologies, Inc.
3300 University Blvd., Suite 140
Winter Park, FL 32792

Re: K001144
Trade Name: UltraEdge Keratome Blade
Regulatory Class: I
Product Code: 86 HNO
Regulation: 886.4370
Dated: April 7, 2000
Received: April 10, 2000

Dear Mr. Mirza:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic, Ear, Nose and
Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION III

Statement for Indications for Use

510(k) Number (If known): K001144

Device Name: UltraEdge Keratome Blade

The **UltraEdge Keratome Blade (Model No. 374803 – ACS)** is a single-use replacement blade for use with AC-powered Chiron Vision ACS Keratome System that is intended to shave a partial lamellar resection of the cornea.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001144

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)